510(k) Summary as required by section 807.92(c)

Date: 6/27/12

K-number: K103577

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JUL 3 2012

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Trade name:
Trinon Q an Q^3 implant system

Common name:
One-piece implant system

Classfication name:
Endosseous dental implant, Dental (21 CFR 872.3640- DZE)

Predicate Devices:
K062281, K061717, K052997– Zimmer Dental Inc. , 1900 Aston Ave., Carlsbad, CA 92008

Description of the Device:
This low-cost implant system was developed to cover many indications in implant dentistry. Designed to provide simplicity and clarity, TRINON TITANIUM GmbH has created a system that removes many of the disadvantages of earlier implant systems. This single-phase enossal implant is made of titanium and there are no complex components. Its self-cutting thread allows the immediate placement of a temporary crown. The transgingival healing makes a second operation unnecessary.
The application areas are telescopic and conical crowns, crowns and bridges, and ball attachment restorations.

Our one-piece implant system line is divided into the Q-implant system and the Q^3 implant-system. The top of the Q-implant system was designed with a 7° cone, whereas the Q^3-implant sytem is a one-phase implant with a ballpoint-head. The TRINON Q- and Q^3 Implants and its components are available in the lengths 8, 10, 12 and 14mm and diameters 3.5 and 4.5mm.

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Indication range:
For single and multiple tooth replacement in the upper and lower jaw. Adequate bone quality, width and height must be available. It has to be proven carefully, if the systemic state of the patient is adequate for an implantation, and especially if there are any allergic reactions on the implant components as well as any prohibitive diseases (e.g. diabetes, smoker).

Indications for Use:
Trinon Q & Q³ Implant System is indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Trinon Q & Q³ Implant System might be loaded in the anterior mandibular arch if four are splinted together with a bar.

Comparison with Predicate Devices:
The Trinon product is similiar to the Predicate Devices in terms of technical characteristics, design, Indications for Use, target population, where it is used, performance, biocompatibility characteristics as well as sizes and configurations. Similar as the Zimmer predicate devices the Trinon implants are one-piece constructions, have an integral, pre-contoured abutment, a tapered implant body, a titanium alloy construction, self-cutting thread, and an implant head with symmetrical, axially directed grooves.

Relevant Areas	***TRINON Q- and Q³-implant system***	***Result***	***Zimmer One-Piece Implant (straight & angled)***
Intended Use Indications for use	Trinon Q & Q³ Implant System is indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Trinon Q & Q³ Implant System might be loaded in the anterior mandibular arch if four are splinted together with a bar.	s.e.	*Zimmer®* One-Piece 4.7mm, Straight implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. *Zimmer®* One-Piece 4.7mm, Straight implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The *Zimmer®* One-Piece 4.7mm, Straight implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.
Material	TRINON Q-Implants are made of Titanium	s.e.	Identical
Target population	Professional use only – qualified dental implantologists, oral surgeons or maxilla surgeons only. Strictly reserved to specialised and trained users.	s.e.	Identical
Where used	Dental practises	s.e.	Dental practises
Design	All implants are delivered in a double blister packaging for sterile handling. They come in a polypropylene sleeve, supported by a polypropylene plug. The sleeve with the implant is sealed in a double transparent blister, the outer blister of which is supplied with a sandwich tag for transference to the patient file (LOT No.)	s.e.	Identical
Performance / Biocompatibility	Testing according ISO 10993 Biological Evaluation of Medical Devices applying all relevant provisions for the devices. All relevant testing regarding biocompatibility was carried out by TRINON TITANIUM GmbH with a total compliance with the provisions of ISO 10993.	s.e.	The same material is used for the predicate devices manufactured and distributed by Zimmer Dental Inc., Carlsbad, CA 92008, USA, which received market clearance and are in commercial distribution.
Sterilisation	Implants, drills and other invasive components are sold and used sterile. All other components and accessories are sold non-sterile.	s.e.	Identical
Design, Sizes, Shades	TRINON Q- and Q³ Implants and its components are available in the following	s.e.	Zimmer One-Piece implants (straight & angled) and its components are available in the following

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lengths and diameters: Diameter: Ø 3.5 and 4.5mm Length: 8, 10, 12 and 14mm	lengths and diameters: Diameter: Ø 3.0, 3.7 and 4.7mm Length: 10, 11.5, 13 and 16mm

Conclusion: The Trinon product can be deemed substantially equivalent for its indicated use.

Summary of the non-clinical Tetsing Data

Results of risk analysis, case studies, cleanliness testing, biocompatibility, sterilization, cytotoxicity and packaging testing have demonstrated that TRINON Q- and Q³ Implants are equivalent to the predicate device implants tested. When compared with predicate devices, results of bench performance testing indicated all acceptance criteria were met, and demonstrated the subject implants are equivalent.
A series of safety and performance testing were performed to demonstrate that the TRINON Q- and Q³ Implants do not raise any new issues of safety and efficacy.

Summary

The presented data that was conducted on the Trinon products shows in its results and in comparison to the predicate devices substantially equivalent to predicate devices for their intended use. All models that are covered by this 510(k) premarket notification have been on the market in Europe for many years with no device failures. The used materials are well researched.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K103577
Trade/Device Name: Trinon Q & Q^3 Implant System (One-Piece Implant System)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 28, 2012
Received: July 2, 2012

Dear Mr. Denk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number:
K103577

Device Name:
Trinon Q & Q³ Implant System (One-Piece Implant System)

Indications for use:
Trinon Q & Q³ Implant System is indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Trinon Q & Q³ Implant System might be loaded in the anterior mandibular arch if four are splinted together with a bar.

Prescription Use **X** AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of DCRH, Office of Device Evaluation (ODE)

Rheinabtrun for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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